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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,804	02/22/2002	Lisa C. McConlogue	MBHB02-329-A	2073
20306	7590	01/25/2005	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP			CROUCH, DEBORAH	
300 S. WACKER DRIVE			ART UNIT	
32ND FLOOR			PAPER NUMBER	
CHICAGO, IL 60606			1632	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,804

Applicant(s)

MCCONLOGUE ET AL.

Examiner

Deborah Crouch, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9 and 13-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9 and 13-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/22/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's arguments filed October 28, 2004 have been fully considered but they are not persuasive. The amendment has been entered.

Claims 1-6, 9 and 13-52 are pending.

Applicant's arguments and amendments to the claims have overcome the rejections made under 35 U.S.C. § 102 and 103 set forth in the previous office action mailed June 28, 2004.

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9 and 13-52 remain rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility for reasons set forth in the rejection mailed June 28, 2004.

Claims 1-6, 9 and 13-52 lack either a specific or substantial utility.

Claims 1-6, 9 and 13-52 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant argues that the claims have a specific utility in that the claimed animals can be used to screen for inhibitors of β -secretase activity, inhibitors of other proteases and assay for side effects of inhibitors. Applicant argues that these uses of

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the animals and methods are useful in identifying therapeutics for the treatment or prevention of Alzheimer's disease. Applicant argues that the specification clearly correlates proteolytic cleavage of APP with Alzheimer's disease, and that BACE-1 is one of the proteases, which cleaves APP, but other proteases are involved as well. Applicant argues that identification and characterization of inhibitors of these proteases is useful in identifying therapeutics for the treatment or prevention of Alzheimer's disease. Applicant argues that the claims have a substantial utility as the animals and methods of assay are relevant to development of therapeutics for the treatment or prevention of Alzheimer's disease. These arguments are not persuasive.

The identification of inhibitors of other proteases involved with the onset of Alzheimer's disease does not constitute a specific utility as it is not specific to BACE-1 knockout animals. Such identification can be accomplished with any other animal, which exhibits proteolytic cleavage of APP associated with Alzheimer's disease. The specification does not disclose a utility specific for the animals, products from the animals or methods claimed. The claims also lack substantial utility because there is no disclosure as how the results would be used without further experimentation.

Claims 1-6, 9 and 13-52 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement for reasons set forth in the office action mailed June 28, 2004. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Two methods for producing BACE1 null mice are disclosed in the specification; one method using nuclear transfer technology and the other method using ES cell technology. Neither of these methods was enabled at the time of filing for the breadth of nonhuman animal as discussed immediately below.

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Applicant argues that the examiner points out that an article on cloning technology which predates the present application, Westhusin, states that the basic methodology for nuclear transfer is similar across species, and then goes on to identify six factors that are relevant to successful cloning. Applicant argues that the specification discloses the nuclear transfer method is useful for the production of non-murine animals. These arguments are not persuasive.

Applicant has not provided arguments or evidence as to why the claims as related to nuclear transfer are enabled. Applicant has not rebutted any of the examiner's arguments with regard to Westhusin or any of the other cited references. The argument set forth by the examiner is that more than a basic outline of nuclear transfer was needed at the time of filing to make animals by that method.

Applicant argues that ES cell technology is disclosed as the preferred method of producing null mutant murine animals and that the specification teaches the production of BACE-1 null mutant mice using this technology. This argument is not persuasive.

The examiner acknowledged the production of transgenic mice whose BACE-1 gene had been disrupted through the use of ES cell technology (office action mailed June 28, 2004, page 10, parag. 1). However, applicant's claims are not so limited. Further, "murine" encompasses more than "mouse" but included many rodent type animals. The only ES cells known in the art at the time of filing that colonized the germ line were for mice.

The claims are free of prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.
Primary Examiner
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January 20, 2005